



**UNITED STATES DEPARTMENT OF COMMERCE
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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/181,671	10/29/98	MEISEL	PM256866

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EXAMINER

DAVIS, B

ART UNIT

1621

PAPER NUMBER

6

DATE MAILED:

10/20/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/181,671

Applicant(s)

Meisel et al.

Examiner

Brian J. Davis

Group Art Unit

1621



☒ Responsive to communication(s) filed on applicant's amendment received 8/26/99 (Paper No. 5)

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3 and 16 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 and 16 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☒ received in Application No. (Series Code/Serial Number) 09/004,926.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1621

DETAILED ACTION

Specification

1. The objection to the disclosure, because of the use of the abbreviation '[sic]', is withdrawn in response to applicant's amendment received 8/26/99 (Paper No. 5). The amendment deletes the cited instances of '[sic]' from the text.

Claim Objections Withdrawn

2. The objection to claims 3 and 15, because of the use of the abbreviation '[sic]', is withdrawn in response to applicant's amendment above. The amendment deletes the cited instance of '[sic]' from claim 3. The amendment cancels claim 15.

112 and 101 Rejections Withdrawn

3. The rejection of claim 15 under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 101 is withdrawn in response to applicant's amendment above. The amendment cancels claim 15.

102 Rejections Withdrawn

4. The rejection of claim 1-3, 15 and 16 under 35 U.S.C. 102 is withdrawn in response to applicant's amendment above. The amendment cancels claim 15. With regard to the other claims, *vide infra*.

Art Unit: 1621

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-3 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over DE 4200259, cited in the previous Office Action, and further in view of the *Kirk-Othmer Encyclopedia of Chemical Technology*, 4th ed., Vol. 7, 1993, pp. 700-702.

8. As was stated in the previous Office Action, applicants admit on page 1 lines 24-29 of the specification, that the compound of formula I is well known in the cited art, as is its use in pharmaceutical compositions. Applicants also admit, on lines 31-35 of page 1 of the specification, that crystallization produces different product mixes with regard to crystal size and form. This

Art Unit: 1621

was the basis for the examiner's assertion that the three crystalline morphologies - A, B and C - of the compound of formula I are inherent in the prior art.

9. Applicants argue in the amendment that the three crystalline morphologies are not inherent in the cited prior art. Having carefully considered applicant's argument, the examiner is in agreement that the inherency alluded to in the cited prior is an insufficient argument to support the previous 102 rejection - based on just the cited prior art. However, as the *Kirk-Othmer Encyclopedia* reference makes clear, a standard reference text and one which one of ordinary skill in the art would be familiar, the instant crystalline morphologies would have been obvious to one of ordinary skill in the art.

10. To reiterate, the instant compound is taught in the cited prior art, and applicant admits as much. It is neither new nor novel, nor is its claimed use. The fact that the compound crystallizes in three distinct crystalline forms, an instance of polymorphism, does not render the compound in these crystalline forms patentable over the compound itself. Polymorphism, *Kirk-Othmer Encyclopedia of Chemical Technology*, 4th ed., Vol. 7, p. 702, is a condition in which a specific chemical compound may crystallize in different forms, that is, different space groups and with different physical and physico-chemical properties. An example is given of a simple compound, ammonium nitrate, with four form changes. In the paragraph with follows, it is stated that a specific polymorph may be absolutely essential for a particular crystalline product. By way of example, it is generally stated that one polymorph may have more desirable physico-chemical properties i.e. color, hardness, solubility or stability than another.

Art Unit: 1621

11. As this section of the *Kirk-Othmer Encyclopedia* makes quite clear, it is generally known in the chemical arts that many compounds crystallize in two or more distinct forms, morphologies, and that these forms will have distinct properties with some forms, because of those properties, being more desirable/useful than others.

12. The instant crystalline forms compound I are not patentably distinct over the cited prior art.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The *Kirk-Othmer Encyclopedia of Chemical Technology*, 3rd ed., Vol. 7, 1979, pp. 251-255 is cited to show the definition of crystalline habit.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Brian Davis whose telephone number is (703) 305-7129. The examiner can normally be reached M-F from 8 to 4:30.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached M-F from 8:30 to 5 at (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

16. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



GARY GEIST
SUPERVISORY PATENT EXAMINER
TECH CENTER 1600

Serial Number: 09/181,671

Page 6

Art Unit: 1621

13/ 7 ✓
Brian J. Davis

date: *10/14/99*